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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/697,719 | 10/27/2000 | Hiroki Nakajima | 20-4764P | 4838 |

2292 7590 03/23/2004

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| EXAMINER |
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KRUSE, DAVID H

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| ART UNIT | PAPER NUMBER |
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1638

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/697,719

Applicant(s)

NAKAJIMA ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 8-19, 26, 27, 32-36, 38-42, 44, 46, 48, 50 and 52-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 20-25, 28-31, 37, 43, 45, 47, 49 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/302,357.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/00&2/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group VI, claims 1-7, 20-25, 28-31, 37, 43, 45, 47, 49 and 51 in the response filed 2 January 2004 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden to rejoin the claims when the claims share the same classification (page 3, 1st paragraph of the Response). This is not found persuasive because the nature of the herbicide resistance encompassed by each of the Groups is distinct and would require different art searches, even though the classification is the same. Applicant argues that Groups VI and VII should be rejoined based on their identical subclassifications and would only require the addition of claims 26 and 27 to the claims of elected Group VI (page 3, 2nd paragraph of the response). This is not found persuasive because after examination of the different inventions of Groups VI and VII, the Examiner has determined that they are directed to different and distinct inventions and would require separate searches of the art. Those claims generic to more than one invention will be examined to the extent that they read on the elected invention.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 8-19, 26, 27, 32-36, 38-42, 44, 46, 48, 50 and 52-69 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **with** traverse in the response filed 2 January 2004.

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3. This application contains claims 8-19, 26, 27, 32-36, 38-42, 44, 46, 48, 50 and 52-69 drawn to an invention nonelected with traverse in the response filed 2 January 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144) See MPEP § 821.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Priority

5. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification and in an application data sheet (37 CFR § 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Information Disclosure Statement

6. The information disclosure statements filed 27 October 2000 and 9 February 2001 have been considered, signed copies are attached hereto. In the IDS filed 27

October 2000, the Derwent Abstract reference is improper. The Examiner has corrected the PTO-1449 to list the WIPO Document under Foreign Patent Documents.

Drawings

7. The Drawings are acceptable to the Examiner.

Specification

8. The abstract of the disclosure is objected to because it is not directed to the elected subject matter and is in the form of a claim. Correction is required. See MPEP § 608.01(b).

9. The title of the invention is not descriptive of the elected invention. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

10. The specification is objected as failed to comply to 37 CFR § 1.73 as follows:

37 CFR § 1.73 Summary of the invention. A brief summary of the invention indicating its nature and substance, which may include a statement of the object of the invention, should precede the detailed description. Such summary should, when set forth, be commensurate with the invention as claimed and any object recited should be that of the invention as claimed

In the instant specification, pages 16-48, the full listing of the originally presented claims are present, and not a brief summary of the invention. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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12. Claims 1-7, 20-25, 28-31, 37, 43, 45, 47, 49 and 51 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it does not distinctly claim the subject matter, said claim reciting general function of a protein encoded by a gene and excluding a gene encoding an immunoglobulin. The limitation "having a specific affinity for a substance which is concerned with the weed control activity of a weed control compound" and "having substantially no capability of modifying a substance for which said protein has a specific affinity" are indefinite limitations and do not state the metes and bounds of the claimed method. Claims 2-7, 20-25, 28-31, 37, 43, 45, 47, 49 and 51 are similarly indefinite because they do not clarify the indefiniteness of claim 1 or are similarly indefinite, see also claim 28. The claims in general appear to be a literal translation from the Japanese priority documents and do not conform to standard US claim language. Appropriate correction is required.

At claim 2, line 2, "the form" lacks adequate antecedent basis within the claim or in claim 1.

At claims 22-25, line 2, the limitation "a variant" renders the claim indefinite because it is unclear what the metes and bounds of "variant" are.

At claim 45, line 2, "the weed control compound" lacks antecedent basis in claim 43, directed to a plant.

13. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-7, 20-25, 28-31, 37, 43, 45, 47, 49 and 51 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a method for giving resistance to weed control compounds to plants which comprises the steps introducing a gene encoding a protein having the following characteristics (a) to having a specific affinity for a substance which is concerned with the weed control activity of a weed control compound, having substantially no capability of modifying a substance for which said protein has a specific affinity, and being substantially free from framework regions of variable regions in an immunoglobulin, into a plant cell; and expressing the gene, wherein said gene encodes a protoporphyrinogen IX oxidase (Protox) derived from soybean and lacking the ability to oxidize protoporphyrinogen IX. Applicant also claims a transgenic plant produced by said method and method of using said transgenic plant.

Applicant describes a method of making a transgenic plant comprising transforming said plant with a polynucleotide encoding a soybean protoporphyrinogen IX oxidase enzyme wherein the chloroplast transit signal and FAD binding sequence had been deleted (examples 11-14 on pages 142-147 of the specification).

Applicant does not describe the genus of polynucleotides encoding a variant protoporphyrinogen IX oxidase having no capability of oxidizing protoporphyrinogen IX

and having a specific affinity for a Protox inhibitory-type herbicidal compound required to practice the claimed methods or make the claimed plant.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

15. Claims 1-7, 20-25, 28-31, 37, 43, 45, 47, 49 and 51 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of making a transgenic plant comprising transforming said plant with a polynucleotide encoding a soybean protoporphyrinogen IX oxidase (Protox) enzyme wherein the chloroplast transit signal and FAD binding sequence (GXGXXG) had been deleted, does not reasonably provide enablement for a method of making a transgenic plant comprising transforming said plant with a polynucleotide encoding any variant protoporphyrinogen IX oxidase enzyme having no capability of oxidizing protoporphyrinogen IX and having a specific affinity for a Protox inhibitory-type herbicidal compound. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a method for giving resistance to weed control compounds to plants which comprises the steps introducing a gene encoding a protein having the following characteristics (a) to having a specific affinity for a substance which is concerned with the weed control activity of a weed control compound, having substantially no capability of modifying a substance for which said protein has a specific affinity, and being substantially free from framework regions of variable regions in an immunoglobulin, into a plant cell; and expressing the gene, wherein said gene encodes a protoporphyrinogen IX oxidase (Protox) derived from soybean and lacking the ability to oxidize protoporphyrinogen IX. Applicant also claims a transgenic plant produced by said method and method of using said transgenic plant.

Applicant teaches a method of making a transgenic plant comprising transforming said plant with a polynucleotide encoding a soybean protoporphyrinogen IX oxidase enzyme wherein the chloroplast transit signal and FAD binding sequence had been deleted (examples 11-14 on pages 142-147 of the specification).

Applicant does not teach the genus of polynucleotides encoding a variant protoporphyrinogen IX oxidase having no capability of oxidizing protoporphyrinogen IX and having a specific affinity for a Protox inhibitory-type herbicidal compound required to practice the claimed methods or make and use the claimed plant.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be

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necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance on how to make and use polynucleotides encoding variant Protox enzymes having no capability of oxidizing protoporphyrinogen IX. Applicant has only provided guidance on how to make and use polynucleotides encoding Protox enzymes having the GXGXXG consensus sequence for an FAD binding domain, wherein said domain is deleted, thus preventing activity of the encoded Protox enzyme but not prevent binding in the substrate binding site, either to an inhibitor or to protoporphyrinogen IX. The nature of the art is such that it is well established that the primary, secondary and tertiary structure of a protein determines its function (see Lehninger 1982, in Principles of Biochemistry, page 209). Without extensive guidance by Applicant, one of skill in the art at the time of the invention would have required undue trial and error experimentation to make and use polynucleotides encoding a broad genus of variant Protox enzymes having the recited properties. In fact, one of skill in the art could envision that changes in the primary structure of a Protox enzyme could prevent FAD from binding without removing the GXGXXG consensus sequence by making a localized change in the primary and tertiary structure of the protein. But, without extensive guidance one of skill in the art would have been required to practice

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undue trial and error experimentation to make and use polynucleotides encoding such modified Protox enzymes.

Conclusion

16. Claims 1-7, 20-25, 28-31, 37, 43, 45, 47, 49 and 51 are free of the prior art which neither teaches nor fairly suggests a polynucleotide encoding a Protox enzyme variant having no capability of oxidizing protoporphyrinogen IX and having a specific affinity for a Protox inhibitory-type herbicidal compound, method of using said polynucleotide or transgenic plants transformed with said polynucleotide.

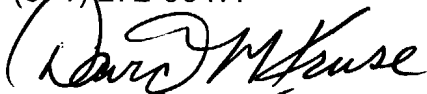
17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is

(571) 272-0547.


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David H. Kruse, Ph.D.
22 March 2004